

REMARKS

Claims 91-95 and 98-112 constitute the pending claims in the present application. Applicants respectfully request reconsideration of the rejections of record in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the Office Action.

Interference Decisions

The Examiner requested information regarding the claimed subject matter. Applicants herewith submit decisions for all of the interference decisions related to p16.

1. With respect to Interference No. I 104, 469, Applicants herewith submit Appendix A which contains a Request for Reconsideration Under § 1.658(b) by Cold Spring Harbor with respect to count 2 of the interference. Part of Appendix A is the Grant of Cold Spring Harbor's request ordered on November 20, 2001.

Count 2 of the interference included:

- Claim 17 of the Beach '169 patent (Appendix B)
- Claim 14 of the Beach '316 patent (Appendix C)
- Claims 1-3, 8-9, 12-13, and 47-48 of Carson Application No. 08/227,371.

Specifically, Cold Spring Harbor was determined not to be entitled to a patent containing claim 17 of U.S. Patent 5,889,169, which corresponds to count 2; or a patent containing claim 14 of U.S. Patent 5,962,316, which corresponds to count 2.

Claim 17 of U.S. Patent 5,889,169 recites "The recombinant gene of claim 15, which is derived from a genomic clone and includes intronic nucleotide sequences disrupting said nucleotide sequence of a nucleic acid sequence of SEQ ID No: 1".

Claim 14 of U.S. Patent 5,962,316 recites "The nucleic acid of claim 12, which nucleotide sequence includes at least one intronic nucleotide sequence disrupting said open reading frame".

Cold Spring Harbor was determined to be entitled to a patent containing claims 1-16 and 18-29 of U.S. Patent 5,889,169 and to a patent containing claims 1-13 and 15-40 of U.S. Patent 5,962,316. Please see the respective patents for the entitled claims.

Claims 1-16 and 18-29 of the '169 patent are drawn to a substantially pure nucleic acid; a recombinant gene; a substantially purified nucleic acid, and an isolated nucleic acid which encode a p16 polypeptide.

Claims 1-13 and 15-40 of the '316 patent are drawn to an isolated nucleic acid and an isolated recombinant gene encoding a polypeptide including an INK4 amino acid sequence which specifically binds to and inhibits a CDK; an expression vector, a host cell, a nucleic acid composition, a recombinant transfection system, and a method of producing a recombinant peptide.

2. With respect to Interference No. I 104,009, Applicants herewith submit Appendix D which is the decision for Alexander Kamb, Junior Party (Application 08/481,063) v. Dennis A. Carson and Tsutomu Nobori, Senior Party (Application No. 08/227,800).

The claims of the Kamb Application No. 08/481,063 involved in the count are drawn to a method for diagnosing or prognosing tissue of a lesion in a mammal comprising detecting a somatic alteration of wild-type MTS1 gene or its expression products; or confirming lack of neoplasia at the MTS1 locus comprising detecting wild-type MTS1 gene or its expression products.

The Board of Patent Appeals and Interferences decided that junior party Alexander Kamb was not entitled to a patent containing claims 1, 5, 8, 11-15, and 23-30 (corresponding to Count 2) of application 08/481,063, filed June 7, 1995.

3. With respect to Interference No. I 104,468, Applicants herewith submit Appendix E which is the decision for Alexander Kamb, Junior Party (Application No. 08/986,147) v. Cold Spring Harbor Laboratory, Senior Party, (Patent Nos. 5,962,316 and 5,889,169).

Count 1 of the interference included:

- Claims 1-16 and 18-29 of the Beach '169 patent
- Claims 1-13 and 15-40 of the Beach '316 patent
- Claims 1-2, 8, 18-19, 26-29, and 33-35 of Kamb Application No. 08/986,147.

The Board of Patent Appeals and Interferences determined that priority as to Count 1 is awarded against Kamb; that Kamb was not entitled to a patent containing claims 1, 2, 8, 18, 19,

26-29, and 33-35, (corresponding to Count 1) of application 08/986,147; and Cold Spring Harbor Laboratory was determined to be entitled to a patent containing claims 1-16 and 18-29 of U.S. Patent 5,889,169 and to a patent containing claims 1-13 and 15-40 of U.S. Patent 5,962,316.

The subject matter of the Beach et al. patents have been described *supra*.

The claims of the Kamb Application involved in the count were drawn to an isolated DNA fragment comprising cDNA coding for an MTS1 polypeptide; a cloning vector, and an expression system.

Additionally, Applicants point out that the Kamb Application No. 08/986,147 is a continuation-in-part of application Ser. Nos. PCT/US95/03316, filed Mar. 17, 1995, Ser. No. 08/251,938, filed Jun. 1, 1994, Ser. No. 08/215,087, filed Mar. 18, 1994, and Ser. No. 08/215,086, filed Mar. 18, 1994. Application Ser. No. 08/251,938, filed Jun. 1, 1994, in turn is a continuation-in-part of application Ser. No. 08/214,582, filed Mar. 18, 1994.

Applicants note that that the Kamb patent cited in the 102(e) rejection contains the same claim of priority to March 18, 1994 of Kamb Application No. 08/986,147.

4. With respect to Interference No. I 104,470, Applicants herewith submit Appendix F which is the decision for Alexander Kamb, Junior Party (Application 08/481,063) v. David H. Beach, Douglas J. Demetrick, Manuel Serrano and Gregory J. Hannon and David H. Beach, Douglas J. Demetrick, Manuel Serrano and Gregory J. Hannon, Dawn E. Quelle and Charles J. Sherr, Senior Party (Patents 5,889,169, and 5,962,316).

Count 1 of the interference included:

- Claim 17 of the Beach '169 patent
- Claim 14 of the Beach '316 patent
- Claims 1, 6, 8, 11-15, and 23-30 of Kamb Application 08/481,063.

The Board of Patent Appeals and Interferences determined that priority as to Count 1, the sole count in the interference, was awarded against junior party Alexander Kamb. Further, the Board determined that Kamb was not entitled to a patent containing claims 1, 5, 8, 11-15, and 23-30 (corresponding to Count 1) of application 08/481,063, filed June 7, 1995.

Additionally, Applicants note that Beach et al. were determined to be the first inventors because they were the first to conceive and reduce to practice an embodiment within the scope of Count 1 of the interference.

Kamb Application No. 08/481,063 is a continuation-in-part of application Ser. Nos. PCT/US95/03316, filed Mar. 17, 1995, Ser. No. 08/251,938, filed Jun. 1, 1994, Ser. No. 08/215,087, filed Mar. 18, 1994, and Ser. No. 08/215,086, filed Mar. 18, 1994. Application Ser. No. 08/251,938, filed Jun. 1, 1994, in turn is a continuation-in-part of application Ser. No. 08/227,369, filed Apr. 14, 1994, which is a continuation-in-part of application Ser. No. 08/214,582, filed Mar. 18, 1994.

Applicants note that that the Kamb patent cited in the 102(e) rejection contains the same claim of priority of Kamb Application No. 08/481,063.

Drawings

5. The drawings were asserted to fail with respect to compliance with 37 CFR 1.84. Applicants assert that the formal drawings submitted with this response are in full compliance with 37 CFR 1.84.

Related Applications Data

6. The Examiner requested a clarification of the relationship of PCT/US93/09945 to its child and parent applications in the Related Applications section of the instant specification. Applicants have amended the specification accordingly.

Specification

7. Applicants acknowledge acceptance of the new Title.

8. The specification is objected to as allegedly failing to provide proper support for the claimed subject matter in claims 91 and 103 of an "antibody preparation". Applicants have amended the claims to recite "isolated antibody". The specification at page 33, for example, includes the language disclosing isolated polyclonal and monoclonal antibodies. Applicants respectfully request reconsideration and withdrawal of the objection.

Claim Objections

9. Claim 11 is objected to for an informality due to a minor spelling error. Applicants have amended claim 111 to correctly recite -- the anti-CCR antibody --. Applicants assert that the amendment does not narrow the scope of the claimed subject matter. Further, Applicants assert that the correction does not add any new matter and respectfully request reconsideration and withdrawal of the objection.

Claim Rejections – 35 USC § 112, second paragraph

10. Claims 95-97 are rejected under 35 USC 112, second paragraph, because in the recitation of the anti-p16 antibody allegedly lacks insufficient antecedent basis in claim 94, from which claims 95-97 depend.

Applicants have canceled claims 96-97 solely to expedite prosecution of the remaining claims and amended dependent claim 95 to more accurately reflect the language recited in claim 94, from which claim 95 depends. Applicants assert that the amendment does not narrow the scope of the claimed subject matter. Further, Applicants assert that the correction does not add any new matter and respectfully request reconsideration of the rejection.

35 USC §§ 102 and 103

11. Applicants thank the Examiner for clearly stating her position regarding priority dates of the claimed subject matter.

Applicants have amended claims to recite an “isolated antibody” which has support throughout the specification as originally filed, such as on page 33. For example, Applicants disclose that polyclonal anti-CCR antibodies can be isolated from the anti-CCR antisera, e.g., a preparation that is no longer “antisera”.

Applicants assert that the amendment does not narrow the scope of the claims, nor does it constitute new matter.

Applicants respectfully assert that the antibodies as claimed have support in the ‘997 priority document filed December 17, 1992, for example at pages 22-25.

Applicants respectfully assert that the antibodies as claimed have support in the '915 priority document, filed November 18, 1993, for example at pages 24-29.

12. Claims 91-95, 98-99, 101-110 and 112 are rejected under 35 USC 102(e) as being allegedly anticipated by Kamb (US Pat No. 6,090,578, of record). Applicants assert that the earliest effective filing date of Kamb is March 18, 1994.

Applicants have canceled claims drawn to antibody fragments solely to expedite prosecution of the remaining claims. Applicants reserve the right to prosecute any canceled subject matter in a future application.

Applicants assert that Kamb does not teach the invention as claimed for the reasons of record.

Additionally as discussed *supra*, the antibodies as currently claimed are entitled to a priority date as early as December 17, 1992 in the 07/991,997 application, which antedates the effective filing date of the Kamb patent. Thus, Kamb is not available as prior art under 35 USC § 102(e).

Applicants note that that the Kamb patent contains the same claim of priority of Kamb Application No. 08/481,063 and of Kamb Application No. 08/986,147, both of which are presented above in the interference decision section.

Applicants reserve the right to prosecute any canceled subject matter in a future application. Further, Applicants respectfully request reconsideration and withdrawal of the rejection.

13. Claims 91-95, 98-99, 101-110 and 112 are rejected under 35 USC 102(e) as being allegedly anticipated by Skolnick et al. (US Pat No. 5,624,819, of record). Applicants assert that the earliest effective filing date of Skolnick et al. is March 18, 1994.

Applicants have canceled claims drawn to antibody fragments solely to expedite prosecution of the remaining claims. Applicants reserve the right to prosecute any canceled subject matter in a future application.

Applicants assert that Skolnick et al. do not teach the invention as claimed for the reasons of record.

Additionally as discussed *supra*, the antibodies as currently claimed are entitled to a priority date as early as December 17, 1992 in the 07/991,997 application, which antedates the effective filing date of the Skolnick et al. patent. Thus, Skolnick et al. is not available as prior art under 35 USC § 102(e).

Applicants respectfully request reconsideration and withdrawal of the rejection.

14. Claims 91-112 are rejected under 35 USC 103(a) as being allegedly unpatentable over Xiong et al. (*Genes & Dev.* (August 1993); 7: 1572-1583, IDS # EO) in view of Busch et al. (U.S. Patent 4,794,077, of record).

Applicants have canceled claims drawn to antibody fragments solely to expedite prosecution of the remaining claims. Applicants reserve the right to prosecute any canceled subject matter in a future application.

As discussed *supra*, the antibodies as currently claimed are entitled to a priority date as early as December 17, 1992 in the 07/991,997 application, which antedates the August 1993 publication date of Xiong et al. Thus, Xiong et al. is not available as prior art under 35 USC § 102(a).

Applicants assert that the Busch et al. patent alone does not teach each and every limitation of the claims, and in the absence of Xiong et al., cannot anticipate the claimed subject matter or render the claimed subject matter obvious.

Applicants respectfully request reconsideration and withdrawal of the rejection.

15. Claims 96-97 are rejected under 35 USC 103(a) as being allegedly unpatentable over either Kamb (U.S. Patent 6,090,578, of record) or Skolnick et al. (U.S. Patent 5,624,819, of record) in view of Owens et al. (*J. Immunol. Methods* (February 1994); 168-165, of record).

Applicants' position regarding Kamb and Skolnick et al. has been discussed *supra*. The Kamb and Skolnick et al. patents are not available as prior art under 35 USC § 102(e), thereby obviating the rejection under 35 USC § 103(a). Owens et al. do not teach each and every limitation of the claims, and in the absence of Kamb and Skolnick et al., cannot anticipate the claimed subject matter or render the claimed subject matter obvious.

Applicants reserve the right to prosecute any canceled subject matter in a future application and respectfully request reconsideration and withdrawal of the rejection.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945**.

Respectfully Submitted,

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